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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,524	09/29/2006	Hans Naegerl	20802/0205146-US0	1315
7278	7590	09/19/2008		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER YANG, ANDREW	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 09/19/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/599,524	NAEGERL, HANS	
	<b>Examiner</b>	<b>Art Unit</b>	
	ANDREW YANG	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 15,18,19,21 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15,18,19,21 and 23-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to Amendment After Final filed on 8/7/2008. Upon review of the Affidavit filed on 8/7/2008, the Final Rejection mailed on 6/11/2008 has been vacated.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 21, 23-27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (U.S. Publication No. 2002/0035400).

Bryan et al. discloses an intervertebral implant having two outer elements 20, 40 and an intermediate element 60. The intermediate element has an annular closed shape (Paragraph 86), and joins the two outer elements in a restricted, articulated manner such that torsional and shear forces are transmittable (Paragraph 87). The two outer elements have an annular and concave contour (Figures 6 and 7). The two outer elements are joined to the central element 60 in a form fitting manner wherein the contour forms a recess that is oversized relative to the portions of the intermediate member it engages (Figure 6). The recess is considered to be formed by the members 28, 48 and the outer elements 20, 40. The intermediate element is circular and defines an annular central axis (Figure 7). The intermediate element 60 has a cross section

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that is widened in at least one of a sagittal, intermediate, frontal, and a transversal plane (Figure 6). The intermediate element 60 is made of a polymer (Paragraph 88).

Claims 15, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuras (U.S. Patent No. 7169181).

Kuras discloses an artificial intervertebral disc 10 having two outer elements 20, 40, and an intermediate member 60. The intermediate member 60 is annular and joins the outer elements 20, 40 in a restricted articulated manner. The two outer elements have a concave contour on the inner surface and is joined in a former fitting manner to the intermediate member 60. Furthermore, the contour is a recess and is oversized relative to the intermediate element 60 (Figure 8). The intermediate member 60 maybe adhered to the outer elements 20, 40 (column 3, lines 15-17). Thus it can be considered that the adherence material will create a texture on the inner contour of the outer elements that increases friction so as to create a fictional connection between the two outer elements and the intermediate element.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (U.S. Publication No. 2002/0035400).

Bryan et al. discloses the claimed invention except for the polymer material of the central element to be polyethylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the central element of Bryan et al. from polyethylene, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. (U.S. Publication No. 2002/0035400) in view of Kuras (U.S. Patent No. 7169181).

Bryan et al. discloses the claimed invention including a coating of titanium for the outer elements (Paragraph 73). Bryan et al. fails to disclose an anchoring element in the form of anchoring pins that are also coated with a biocompatible material. Kuras teaches outer elements 20, 40 having anchoring pins and also a coating on them to further retain the disc 110 between vertebrae (Column 4, Lines 65-67 and Column 5, Lines 1-5). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Bryan et al. with anchoring pins and a biocompatible coating on the outer elements in view of Kuras in order to further retain the implant between vertebrae.

***Response to Arguments***

Applicant's arguments with respect to claims 15, 18, 19, 21, 23-32 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment Filled on 2/15/2008 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/  
Examiner, Art Unit 3733  
9/15/2008

/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733